IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDTRONIC VASCULAR, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 98-478-SLR
	)	
BOSTON SCIENTIFIC CORP.,	)	
SCIMED LIFE SYSTEMS, INC.,	)	
BOSTON SCIENTIFIC SCIMED,	)	
INC. and MEDINOL, LTD.,	)	
	)	
Defendants.	)	

Karen Jacobs Louden, Esquire, Philip Bangle, Esquire of Morris, Nichols, Arsht & Tunnel, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Raphael V. Lupo, Esquire, Donna M. Tanguay, Esquire, Mark A. Davis, Esquire, James Rizzo, Esquire of McDermott, Will & Emery, Washington, D.C. Counsel for Plaintiff.

Josy W. Ingersoll, Esquire, Christian Douglas Wright, Esquire of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Christopher A. Hughes, Esquire, Richard C. Komson, Esquire, Dorothy R. Auth, Esquire, Israel Blum, Esquire, Steven Meyer, Esquire of Morgan & Finnegan, New York, New York.

MEMORANDUM OPINION

Dated: December 14, 2004
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On August 13, 1998,[1] Arterial Vascular Engineering, Inc. ("Vascular") filed a complaint against Boston Scientific Corporation ("BSC") and Scimed Life Systems Inc. ("Scimed") alleging willful infringement of U.S. Patent Nos. 5,291,331 and 5,674,278 (collectively "the Boneau patents") by the NIR model stents. (D.I. 1) On March 11, 1999, Vascular filed a first amended complaint against Scimed and BSC. (D.I. 17) On June 28, 2000, Medtronic AVE, Inc. ("Medtronic")[2] filed a second amended complaint to add Medinol, Ltd. ("Medinol") as a defendant in the infringement action. (D.I. 62) Medtronic also asserted a third Boneau patent, namely, U.S. Patent No. 5,879,382, and added claims for contributory infringement to the suit. (Id. at ¶ 12)

On July 13, 2000, Medinol answered the second amended complaint, denied all infringement allegations, and asserted numerous affirmative defenses. (D.I. 50) Medinol also filed a counterclaim for a declaratory judgment of invalidity, unenforceability, and noninfringement. (Id.) On February 11, 2004, Medinol filed a motion to dismiss Medtronic's claims against it for lack of subject matter jurisdiction (D.I. 137),

---

[1]On November 15, 2000, this case was stayed pending resolution of two different appeals to the Federal Circuit. (D.I. 245) The case was not reopened until March 20, 2003.

[2]Arterial Vascular Engineering, Inc. amended its complaint on March 11, 1999 to substitute Medtronic AVE as the plaintiff. (See D.I. 17)

which was denied without prejudice to renew. (D.I. 179) On February 20, 2004, Medtronic filed a third amended complaint that added a fourth Boneau patent to the infringment action, specifically, U.S. Patent No. 6,344,053. (D.I. 150)

Presently before the court is Medinol's renewed motion to dismiss Medtronic's claims against it for lack of subject matter jurisdiction, or in the alternative for summary judgment. (D.I. 224) For the reasons that follow, Medinol's renewed motion to dismiss is denied and its motion for summary judgment is denied in part and granted in part.

II. BACKGROUND

Medtronic is a corporation organized under the laws of the State of Delaware with its principal place of business in Santa Rosa, California. (D.I. 50 at ¶ 1) Medtronic manufactures specialized stent delivery systems used in coronary and peripheral applications in the human body. (Id.) Medinol is an Israeli corporation with its principal place of business in Tel Aviv, Israel. (Id. at ¶ 5) Medinol manufactures and sells medical devices, including stents, that are used in the United States. (Id.)

Medinol entered into a supply agreement with BSC on October 25, 1995.[3] (D.I. 225 at Ex. 3) Medinol agreed to supply BSC

[3]The parties dispute how the relationship between Medinol and BSC came about. Medinol claims that BSC convinced it to provide them with the NIR stents. (D.I. 265 at 6-7) Medtronic

with NIR stents to sell worldwide. (D.I. 225) Under the terms of the agreement, Medinol manufactured stents at its plant in Jerusalem, Israel and then delivered the stents to BSC. (Id. at 6, D.I. 225 at Ex. 5, 154) Title and ownership of the NIR stents passed from Medinol to BSC upon shipment of the stents pursuant to the supply agreement. Section 3.05 states:

> Shipment of [s]tents purchased by BSC from Medinol shall be F.C.A. at Medinol's facility for delivery to such of BSC's facilities as BSC shall from time to time designate. All freight, insurance and other shipping expenses relating to such [s]tents, as well as any packing expenses, shall be borne by BSC. Title to and risk of loss for [s]tents purchased by BSC shall pass to BSC upon delivery to the carrier for shipment to BSC or BSC's designated ship destination.

(D.I. 225 at Ex. 2) Under the agreement, Medinol had the right to "participate on a regular basis in strategic discussions with BSC with respect to the marketing, distribution, and sale of [the] [s]tents."[4] Id. at § 2.05. The agreement required the parties to cooperate in obtaining approval from the United States Food and Drug Administration ("FDA"). Section 4.02 states:

> Medinol and BSC agree to cooperate with each other to obtain all FDA approvals necessary for the manufacture,

---

asserts that Medinol sought out BSC to help it market the NIR stent in the United States. (D.I. 254 at 5)

[4]Dr. Jacob Richter testified at his deposition that "to some extent" BSC had given Medinol the opportunity to participate. (D.I. 255 at Ex. O) Documents sent to BSC from Medinol indicate that Medinol was trying to take an active role in marketing. For example, Medinol stated that "[a]ll stent related marketing issues should be coordinated with us so we can help penetrate the market better." (Id. at Ex. Q)

> marketing, distribution and sale of the [s]tents to be sold hereunder in the United States. In connection with the foregoing, Medinol and BSC agree that Medinol and BSC shall submit an application in BSC's name for a premarket approval under the Act ("PMA") in respect of the [s]tents to be sold hereunder in the United States. The PMA shall designate Medinol as an additional manufacturer for purposes of the PMA. At an appropriate time agreed by BSC and Medinol, Medinol and BSC shall submit a PMA supplement to list Medinol as an additional distributor of [s]tents in the United States for purposes of such PMA. If, following the termination of this Agreement, BSC shall retain no license from Medinol hereunder, BSC will assign such PMA to Medinol.

Id. The agreement also divided the risk of patent infringement between Medinol and BCS.[5] Section 9.03 states:

> In the event that the manufacture, use, or sale by BSC of any [s]tents is objected to as infringing a Patent Right held by another party, the out-of-pocket costs and expenses incurred by Medinol and BSC in connection with the defense of any such action will be borne 30% by Medinol (upon receipt of reasonable documentation therefore).

Id.

From 1995 to 1998 Medinol shipped approximately 603 NIR stents to BSC at their Maple Grove, Minnesota address. (D.I. 255 Ex. E) Medinol argues that these stents were "non-commercial" prototypes intended to be used for research and development. (D.I. 225 at 13, 15) According to Medinol's manager Dr. Richter,

[5]In his deposition, Dr. Richter testified that he does not recall whether he was aware of the the Boneau patents before 1998, when Vascular filed the first complaint against BSC. (D.I. 225, Ex. 5, 85) Dr. Richter did read a Boneau patent in 1998, but does not know which one. Id. Based on this, Medinol argues that it was not aware of the Boneau patents until 1998.

the stents could not have been for anything other than research and development because they were not "fit for commercial use from a regulatory point of view." (Id. at Ex. 1, ¶ 2) The majority of the NIR stents were shipped to BSC's facility in Galway, Ireland.[6] (D.I. 225 Ex. 1, ¶ 2) After receiving the stents in Ireland, BSC inspected, cleaned, mounted them on balloon catheters, packaged and sterilized them. (D.I. 225 Ex. 3)

In 1999, Medinol divided its manufacturing processes. (D.I. 225 at Ex. 5, 154) Medinol sent notice to BSC that the NIR stents for the U.S. market would still be manufactured in the old building, but the NIR stents for other markets would be moved to a new building. (D.I 255 at Ex. L) To differentiate between the NIR stents made in each building, Medinol marked the shipments with lot numbers beginning with "1" for U.S. stents and "2" for worldwide stents. (Id. at Ex. M)

In 2001, Medinol filed a lawsuit against BSC in the United States District Court for the Southern District of New York. (D.I. 255 at Ex. A) In its complaint Medinol makes numerous allegations, including breach of contract, delaying the introduction of Medinol's stent into the U.S. market, breach of fiduciary duty and RICO violations. Id. Around February 2002,

[6]On two occasions Medinol sent invoices to BSC's Minnesota office for the stents shipped to Ireland. (D.I. 255 at Ex. G)

Medinol terminated the supply agreement, and discontinued shipping NIR stents to BSC in May 2002. (D.I. 225 at 7, Ex. 5)

III. RENEWED MOTION TO DISMISS

Earlier in the litigation, this court denied Medinol's motion to dismiss for lack of subject matter jurisdiction without prejudice, so Medinol could renew the motion at the close of discovery. At the time, the record was not sufficiently developed to allow the court to decide Medinol's factual challenge to jurisdiction. (D.I. 179) Medinol's renewed motion asserts that it has not performed any infringing activity within the United States, and as such Medinol claims this court does not have subject matter jurisdiction.[7]

A. Standard of Review

The lack of subject matter jurisdiction may be raised at any time; it cannot be waived and the court is obliged to address the issue on its own motion. See Moodie v. Fed. Reserve Bank of NY, 58 F.3d 879, 882 (2d Cir. 1995). Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc., 227 F.3d 62, 69 (3d Cir. 2000).

[7]Although Medinol's arguments could also challenge this court's personal jurisdiction over it, the brief explicitly asserts it is challenging subject matter jurisdiction.

Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). See 2 James W. Moore, Moore's Federal Practice § 12.30[4] (3d ed. 1997). Under a facial challenge to jurisdiction, the court must accept as true the allegations contained in the complaint. See id. Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial and frivolous.'" Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1408-1409 (3d Cir. 1991) (quoting Bell v. Hood, 327 U.S. 678, 682 (1946)).

Under a factual attack, however, the court is not "confine[d] to allegations in the . . . complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." Gotha v. United States, 115 F.3d 176, 179 (3d Cir. 1997). See also Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891-892 (3d Cir. 1977). In such a situation, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." Carpet Group, 227 F.3d at 69 (quoting Mortensen, 549 F.2d at 891). Although the court should determine subject matter jurisdiction at the outset

of a case, "the truth of jurisdictional allegations need not always be determined with finality at the threshold of litigation." Moore at § 12.30[1]. Rather, a party may first establish jurisdiction "by means of a nonfrivolous assertion of jurisdictional elements and any litigation of a contested subject-matter jurisdictional fact issue occurs in comparatively summary procedure before a judge alone (as distinct from litigation of the same fact issue as an element of the cause of action, if the claim survives the jurisdictional objection)." Jerome B. Grubart, Inc. v. Great Lakes Dredge & Dock Co., 513 U.S. 527, 537-38 (1995) (citations omitted).

B. Discussion

Congress vested original subject matter jurisdiction over patent infringement actions under 35 U.S.C. § 271 in the federal district courts. See 28 U.S.C. § 1338(a). Plaintiff's claims are based on a federal law directly within this court's jurisdiction. As discussed below, plaintiff's claims are not frivolous assertions to obtain federal jurisdiction. Therefore, whether Medinol's actions constitute infringement is a matter for this court. As such, Medinol's motion to dismiss for lack of subject matter jurisdiction is denied.

IV. MOTION FOR SUMMARY JUDGMENT

A. Standard of Review

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be

sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

B. Discussion

Medtronic alleges that Medinol directly infringed, contributed to, or induced BSC's infringement of the Boneau patents in violation of 35 U.S.C. § 271.

1. Direct Infringement

Section 271(a) defines infringement as the making, selling, importing or use of any patented invention in the United States without authorization by the patentee. There is a narrow common law exception for de minimis non-commercial use. See e.g., Roche Products v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984). There is also a statutory exception for use "related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1); see also Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

It is undisputed that Medinol's activity within the United States was limited to shipping about 600 noncommercial stents to

Minnesota. It is uncontested that those stents were not intended to be sold in the United States. According to Medinol's agreement with BSC, title to those stents passed to BSC upon shipment. There is no allegation that Medinol operated in the United States; therefore, it never used a NIR stent in the United States. Thus, Medinol did not import, sell, make or use any NIR stents in the United States. As such, there is insufficient evidence to support a finding that Medinol directly infringed the Boneau patents.

2. Contributory Infringement

Contributory infringement occurs when someone:

> [I]mports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringement use . . . .

35 U.S.C. § 271(c). As discussed above, Medinol did not import NIR stents into the United States market. The stents it did send to the United States were not for commercial use. Title to those stents and the other NIR stents sold to BSC transferred to BSC upon shipment. Therefore, there is no evidence of record that would support a finding of contributory activity within the United States.

3. Induced Infringement

Medtronic claims that Medinol induced BSC to infringe the Boneau patents. Under federal law, active inducement of infringement is actionable as infringement. See 35 U.S.C. § 271(b). Since the initial promulgation of § 271(b), federal courts have established four necessary elements of a prima facie case of induced infringement: (1) there was direct infringement by the induced party; (2) the inducer had knowledge of the asserted patents; (3) the inducer "possessed specific intent [and] not merely . . . knowledge of the acts alleged" to induce; and (4) there was active inducement of the direct infringer. Ferguson Beauregard/Logic Controls v. Mega Sys., 350 F.3d 1327, 1342 (Fed. Cir. 2003); see also generally Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003); Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558 (Fed. Cir. 1994); Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464 (Fed. Cir. 1990); Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544 (Fed. Cir. 1990).

a. BSC's Direct Infringement

Plaintiff's claims of infringement by BSC are scheduled for trial in 2005. Because issues of material fact exist, it is inappropriate to dismiss this claim on summary judgment. Because a finding of direct infringement by BSC would not be dispositive of this issue, the court considers the three other requirements.

b. Medinol's Knowledge of the Boneau Patents

From the record it is unclear how much Medinol knew about the Boneau patents. Dr. Richter was unsure if he had read a Boneau patent before 1998; he was certain that he read one in 1998 but unsure which one he read. Because the evidence is unclear with respect to when and what Medinol knew about the Boneau patents, the issue should be determined by the finder of fact for this case.

c. Medinol's Intent to Induce

Direct evidence of intent is not required; circumstantial evidence may be sufficient proof. See Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 669 (Fed. Cir. 1988). There is evidence that Medinol intended for BSC to sell NIR stents in the United States. Medinol tried to take an active role in marketing the stents in the United States. Medinol agreed to help BSC seek FDA approval for the stents. At some point, Medinol began selling stents to BSC that were specifically intended for the United States market. If a jury found that Medinol knew about the Boneau patents at the time it was selling stents to BSC, the jury could reasonably infer that Medinol intended for BSC to infringe the patents.

d. Active Inducement of BSC

It is disputed whether Medinol sought out BSC to gain access to the United States stent market. Neither party presents

evidence about how the agreement between BSC and Medinol was negotiated. Without direct evidence on point, a reasonable jury could conclude that Medinol did induce BSC's infringement because it actively produced NIR stents specifically for, and took an active role in marketing the NIR stents for, the United States market.

V. CONCLUSION

For the reasons stated, Medinol's motion to dismiss for lack of subject matter jurisdiction is denied. Medinol's motion for summary judgment is granted with respect to plaintiff's claims of direct and contributory infringement. Medinol's motion for summary judgment is denied with respect to plaintiff's claims of induced infringement. An order consistent with this memorandum opinion shall issue.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDTRONIC VASCULAR, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 98-478-SLR
	)	
BOSTON SCIENTIFIC CORP., SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC SCIMED, INC. and MEDINOL, LTD.,	)	
	)	
Defendants.	)	

O R D E R

At Wilmington this 14th day of December, 2004, consistent with the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Defendant Medinol's motion to dismiss for lack of subject matter jurisdiction (D.I. 224) is denied.

2. Defendant Medinol's motion for summary judgment (D.I. 224) is granted with respect to:

a. Plaintiff's claims of direct infringement; and

b. Plaintiff's claims of contributory infringement.

3. Defendant Medinol's motion for summary judgment (D.I. 224) is denied with respect to plaintiff's claims of induced infringement.

Sue L. Robinson
United States District Court